COMMONWEALTH OF MASSACHUSETTS
EXECUTIVE OFFICE OF ENVIRONMENTAL AFFAIRS
DEPARTMENT OF ENVIRONMENTAL PROTECTION
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Commissioner

MASSACHUSETTS AIR POLLUTION CONROL REGULATIONS 310 CMR 7.00 et seq.

Regulations for the Control of Air Pollution in the Berkshire Air pollution Control District Pioneer Valley Air Pollution Control District Merrimack Valley Air Pollution Control District Metropolitan Boston Air Pollution Control District Central Massachusetts Air Pollution Control District Southeastern Massachusetts Air Pollution Control District

PUBLIC HEARING DRAFT

Plan Approval Exemptions for Biotechnology Laboratories and Surface Disinfection Processes

May 2005

Prepared by: ***The Commonwealth of Massachusetts***
Executive Office of Environmental Affairs
Department of Environmental Protection
Bureau of Waste Prevention

May 2005

Dear Citizen:

I am pleased to send you this copy of the public hearing draft of proposed amendments to the Massachusetts air quality control regulations.

After reviewing this public hearing draft, I hope that you will comment and attend one of the six public hearings to be held by the Department June 23 through 30, 2005; the public comment period will end on July 11, 2005. The Department would like to receive your comments and suggestions on how we can most effectively implement the hazardous waste program.

Please contact Bob Donaldson (617) 292-5619 or Lee Dillard Adams (508) 767-2775 if you have questions you would like to ask prior to the hearings. We hope you can attend and look forward to receiving your input.

Very truly yours,

James C. Colman
Assistant Commissioner
Bureau of Waste Prevention

The Commonwealth of Massachusetts
Executive Office of Environmental Affairs
Department of Environmental Protection
and the Board of Certification of Operators of Wastewater Treatment Facilities

PUBLIC HEARINGS NOTICE

The Department of Environmental Protection is holding public hearings on proposed amendments to: 310 CMR 30.0000, (the Hazardous Waste regulations, adopted pursuant to M.G.L. Chapter 21C); and 310 CMR 7.00 (the Air Quality regulations, adopted pursuant to M.G.L. Chapter 111, §§142 A-N), as well as proposed new regulations at 314 CMR 17.000 (Industrial Wastewater Management for Biotechnology Operations, adopted pursuant to M.G.L. c. 21, §§26 through 53). In addition, the Board of Certification of Operators of Wastewater Treatment Facilities is holding simultaneous public hearings on proposed amendments to 257 CMR 2.00 (the Certification of Operators of Wastewater Treatment Facilities regulations, adopted pursuant to M.G.L. c. 21, §34A and §34B).

The proposed or amended DEP regulations are organized into three regulatory packages.
Amendments to the Hazardous Waste Regulations consisting of:

- Provision for conditional waiver of requirements for elementary neutralization of hazardous waste by Generators in tanks and containers, and
- Provision for a case-by-case waiver determination process that would allow the Department to grant waivers for specific wastes and activities that are either adequately regulated or insignificant as a potential hazard (for wastes and activities not regulated by U.S. EPA under the federal Resource Conservation and Recovery Act);

Amendments to the Air Pollution Control regulations, consisting of:

- Plan Approval exemption for Biotechnology Surface Disinfection Processes, that is intended to provide a permit-by-rule for emission of volatile organic compounds from biotechnology operations' surface disinfection processes; and
- Plan Approval exemption for Biotechnology Laboratories; and

New Industrial Wastewater Management for Biotechnology Operations regulations and an amendment to the Certification of Operators of Wastewater Treatment Facilities regulations:

- These regulatory changes are intended to provide a permit-by-rule for discharge of industrial wastewater to the sewer and for pretreatment of industrial wastewater as well as exempt persons who manage, operate and maintain wastewater treatment facilities in compliance with 314 CMR 17.00 from obtaining a separate approval from the Board of Certification under 257 CMR 2.00.

Public hearings on the proposed amendments will be conducted under the provisions of Chapter 30A of the Massachusetts General Laws on:

Thursday, June 23, 2005 - Springfield - 1:00 p.m. - Department of Environmental Protection, Western Regional Office, 436 Dwight St., Room 305, 3rd Floor Courtroom, Springfield, MA

Friday, June 24, 2005 - Boston - 10:00 a.m. - Department of Environmental Protection, One Winter Street, 2nd Floor, Atlantic Room, Boston, MA

Monday, June 27, 2005 - Worcester - 3:00 p.m. - Department of Environmental Protection, Central Regional Office, 627 Main St., Commissioner's Conference Room, Worcester, MA

Tuesday, June 28, 2005 - Boston – 1:30 p.m. - Department of Environmental Protection, One Winter Street, 2nd Floor, Atlantic Room, Boston, MA

Wednesday, June 29, 2005 - Lakeville - 1:00 p.m. - Department of Environmental Protection, Southeast Regional Office, 20 Riverside Dr., 1st Floor Conference Room, Lakeville, MA

Thursday, June 30, 2005 - Boston - 10:00 a.m. - Department of Environmental Protection, One Winter Street, 2nd Floor, Atlantic Room, Boston, MA

Testimony may be presented orally or in writing at the public hearings. In addition, written comments will be accepted **until 5:00 p.m. on July 11, 2005** at the Department of Environmental Protection, 627 Main Street, Worcester, MA 01608, attention: Lee Dillard Adams.

Copies of the regulation amendments and background documents are available on the DEP website at http://www.mass.gov/dep/bwp/biotech.htm and during normal business hours at the DEP Boston Info Center or DEP's Regional Service Centers:

DEP Boston Info Center, One Winter Street, Boston (800) 462-0444
DEP Southeast Region, 20 Riverside Drive, Lakeville (508) 946-2714
DEP Western Region, 436 Dwight Street, Suite 402, Springfield (413) 784-1100 x 2214
DEP Central Region, 627 Main Street, Worcester (508) 792-7683

This information is available in alternate format upon request to: ADA Coordinator, 4th floor, One Winter Street, Boston, 02108 at (617) 556-1057. For special accommodations for this event, call (617) 348-4056.

By order of the Department

Robert W. Golledge, Jr., Commissioner

I. Background

The Massachusetts Department of Environmental Protection (DEP) is proposing amendments to the Air Pollution Control Regulations (310 CMR 7.00) relative to the biotechnology industry.

Under current regulations, prior to any construction or modification of any process or facility, a determination has to be made whether the operations are subject to DEP air permitting thresholds and if the emissions can be reasonably controlled with air pollution control methods. Emissions from biotechnology laboratories and surface disinfection processes tend to be very small amounts and technically difficult to control with common air pollution control methods except, for best management practices. For these reasons, DEP is proposing to codify, for certain activities of the biotechnology industry, emissions caps and best management practice requirements that would otherwise be applied through individual permits.

However, as always, if a particular facility has the potential to emit pollutants in sufficient amounts or of a particular toxic, 310 CMR 7.02(5)(a)10 of the Air Pollution Control Regulations provides "fail-safe" provisions that allow DEP to regulate any project, regardless of any exemption or permit by rule. A Comprehensive Plan Application is required for any facility, regardless of any exemption established elsewhere in 310 CMR 7.00, that the Department determines has the potential for causing or contributing to a condition of air pollution.

II. Summary of Proposed Regulations

The streamlined requirements are intended for specific activities of the biotechnology industry. Therefore, DEP is proposing a definition of biotechnology to help clarify which companies and activities are covered. The key element in the definition is that products must be derived from living systems. Two exemptions from preconstruction plan approval are being proposed for processes used to make biotechnology products that are regulated by the United States Food and Drug Administration as medical devices, drugs, or biologics.

First, the proposed new 310 CMR 7.02(2)(b)33 would provide an outright exemption for biotechnology laboratories from preconstruction plan approval. Laboratory operations that are utilized for research, development and product support are proposed to be exempt from preconstruction plan approval. Typical emissions from these operations result from the use of miscellaneous solvents for glassware clean up. Emissions from biotechnology laboratories have historically been de minimis (i.e., generally far less than one ton per year of volatile organic compounds) and, as such, would not be subject to 310 CMR 7.02 preconstruction plan approval requirements. This exemption from plan approval provides clarity on this matter.

Second, the proposed new 310 CMR 7.03(25) provides a conditional exemption (i.e. a permit by rule) for biotechnology surface disinfection processes in lieu of preconstruction plan approval by DEP. Biotechnology surface disinfection operations tend to be hand-wiping operations using wipes containing solvents. Emissions are low and are not readily controlled by common air pollution control methods.

The proposed 310 CMR 7.03(25), permit-by-rule, would be available only to companies whose facility-wide emissions are less than 15 tons per year and 2.5 tons per month of volatile organic compounds. Similarly, companies would only be eligible if facility-wide emissions of hazardous air pollutants (HAPS) were under the following limits: emissions of single HAPS are limited to 9 tons per year and 2 tons per month, combinations of HAPS are limited to 15 tons per year and 3 tons per month. The proposed 310 CMR 7.03(25) also would require facilities to keep records of VOC and HAP materials used for each calendar month to demonstrate compliance with the total facility-wide emission limits.

Facility-wide emissions are calculated by totaling emissions from all sources within the facility, regardless of whether the sources are subject to preconstruction plan approval or exempt from it. Therefore, emissions from a biotechnology laboratory, which would be exempt from a 310 CMR 7.02 plan approval, would nonetheless have to be calculated into the facility-wide emissions total. This total would need to be below the facility-wide emission limits contained in 310 CMR 7.03(25) for the biotechnology company to be eligible for the permit-by-rule proposed there.

The regulation would require procedures to minimize emissions, and would require that records be kept to verify compliance with the emission limits.

III. Air Quality Impacts

The proposed regulations would have no impact upon air quality as they would merely streamline existing regulatory requirements.

IV. Savings Clause

Any regulatory amendments that affect regulations and programs that are part of the Massachusetts State Implementation Plan (SIP) must demonstrate that they are no less stringent than the existing SIP and that any projected increases in emissions that result from the amendments are offset by equal or greater predicted emission decreases.

The proposed regulation would only allow emissions increases that would have otherwise been allowed through plan approval and these emissions would be de minimis in amount. The proposal would merely codify existing practice. No adverse air quality impacts are projected as a result of these proposed amendments. No compensatory emission decreases need be made.

V. Economic Impacts

The economic impacts can be divided into two categories: administrative costs to the Commonwealth and costs for regulated entities. As a regulatory streamlining initiative, the impact for both parties will be a reduction in costs.

VI. Impact on Small Business

Any impacts upon small business are the same as detailed above.

VII. Agricultural Impacts

Pursuant to the intent of Massachusetts General Laws, Chapter 30A, Section 18, state agencies should evaluate the impact of proposed programs on agricultural resources within the Commonwealth.

As there are no air quality impacts or emission increases associated with these amendments, the proposed amendments are not expected to have any impact on agricultural production in Massachusetts.

VIII. Toxics Use Reduction

Implementation of toxics use reduction is a Department-wide priority. Toxics use reduction is defined as in-plant practices that reduce or eliminate the total mass of contaminants discharged to the environment. These proposed regulations are not expected to have any impact on DEP's efforts. However, DEP seeks comments on two questions: how much acetone is used for glass washing and drying in the industry and whether there is an effective, less toxic alternative to acetone for this use.

IX. Impacts on Cities and Towns

Pursuant to Executive Order 145, the Department must assess the fiscal impact of new regulations on the Commonwealth's municipalities. The Executive Order was issued in response to Proposition 2 ½. The proposed regulations do not affect local government.

X. MEPA

This proposed action is "categorically exempt" from the "Regulations Governing the Preparation of Environmental Impact Reports (301 CMR 11.00)", because the proposed amendments would only streamline existing regulatory practice. All reasonable measures have been taken to minimize adverse impacts.

XI. Public Participation and Request for Comments

These proposed regulations would be subject to public review and comment prior to promulgation. Public hearings to collect comments on the proposed amendments would be conducted under the provisions of Chapter 30A of the Massachusetts General Laws.

After public review and Department evaluation and response to comments, the final amendments would be submitted to the Secretary of State for promulgation. The amendments would also be submitted to the U.S. Environmental Protection Agency for approval as a revision to the Massachusetts State Implementation Plan.

310 CMR 7.00 – Definitions

BIOTECHNOLOGY means the use of cellular and molecular processes from living systems to make or assist in making products.

310 CMR 7.02(2) Exemptions from Plan Approval

(b) Exemptions

33. Biotechnology Laboratory. A laboratory used solely for research, development or support for medical device, drug, or biologic products derived in whole or in part from biotechnology, and such products are either undergoing preclinical research in preparation for, or are the subject of, one of the following U.S. Food and Drug Administration (FDA) regulatory applications or notices: an Investigational New Drug Application, an Investigational Device Exemption Notice, a New Drug Application, premarket approval application, premarket notification pursuant to section 510(k) of the federal Food, Drug and Cosmetic Act (510(k)) and any other product exempted by FDA from the 510(k) premarket notification requirement.

310 CMR 7.03 Plan Approval Exemption: Construction Requirements

(25) Biotechnology Surface Disinfection Processes.

(a) Construction, substantial reconstruction, or alteration of any surface disinfection process used in making any of the following medical device, drug, or biologic products:

1. a product derived in whole or in part from biotechnology, and

2. one of the following applications or notices has been filed with U.S. Food and Drug Administration (FDA) for such product: an Investigational New Drug Application, an Investigational Device Exemption Notice, a New Drug Application, a premarket approval application, or a premarket notification pursuant to section 510(k) of the federal Food, Drug and Cosmetic Act (510(k)) (including an FDA-approved exemption from the 510(k) premarket notification requirement).

(b) Surface disinfection processes shall comply with the following criteria:

1. The total facility-wide actual emissions, including new or modified surface disinfection processes, shall not exceed 15 tons of volatile organic compounds (VOC) per 12-month rolling period. This VOC emission limitation includes all process operations at the facility. In addition, facility-wide actual emissions of VOC shall not exceed 2.5 tons per calendar month.

2. The total facility-wide actual emissions, shall not exceed 9 tons of any single Hazardous Air Pollutants (HAP as defined at 40 CFR Part 63) per 12-month rolling period, and shall not exceed 15 tons of any combination of (total) HAP per 12-month rolling period. In addition, facility-wide

actual emissions of any individual HAP shall not exceed 2 tons per calendar month, and any combination of (total) HAP shall not exceed 3 tons per calendar month.

3. Processes that emit or will emit VOCs or HAPs in exceedance of limitations for VOCs and HAPs established in Subsections (b)1 or (b)2 above, are subject to 310 CMR 7.02(5) Comprehensive Plan Approval (CPA), and a person shall obtain written Department plan approval prior to commencement of construction, installation and operation of said processes.

4. Combustion processes that support processes subject to 310 CMR 7.03(25) are subject to regulatory standards found at 310 CMR 7.02 Plan Approval and Emission Limitations, 310 CMR 7.03 Plan Approval Exemption: Construction Requirements, or 310 CMR 7.26 Industry Performance Standards.

5. Cleaning, sterilization, disinfection, and other operations:

   a. Cleaning, sterilization, disinfection, and other solutions which contain VOC shall be kept in tightly closed containers when not in active use and during transport and storage, and

   b. The spent cleaning cloths and/or wipes used in conjunction with the cleaning and sterilization solutions shall be placed, after use, in tightly closed containers and collected for proper recycling or disposal.

6. Any person subject to this regulatory standard shall maintain records sufficient to demonstrate compliance with 310 CMR 7.03(25) for each calendar month. Records kept to demonstrate compliance with 310 CMR 7.03(25) shall be maintained on-site for five years and shall be made available to representatives of the Department upon request. For each process and operation, such records shall include, but not be limited to:

   a. Gallons of VOC used;
   b. Pounds of VOC used;
   c. Gallons of individual and total HAP used; and
   d. Pounds of individual and total HAP used.